

2. REMARKS/ARGUMENTS

2.1 STATUS OF THE CLAIMS

Claims 8-19, 32-35, 39, 40 and 44-52 were pending at the time of the Action.

Claims 8, 11, 12, 18, 46 and 48 are amended herein.

Claims 8-19 and 44-50 remain pending in the application.

Claims 32-35, 39, 40, 51 and 52 have been indicated as allowable by the present Action.

Reconsideration of the presently-pending claims is respectfully requested in light of the above amendments and the following remarks.

2.2 SUPPORT FOR THE CLAIMS

Complete support for the language of all pending claims can be found throughout the specification and claims as originally filed, and in particular in the reaction schema illustrated beginning on page 16 of the specification, as well as in the description of the ring auxiliaries on pages 34-38 of the specification. Applicants hereby certify that no new matter is incorporated because of the accompanying amendment.

Should any fees be deemed necessary in connection with the entry and consideration of the present paper the Commissioner is hereby authorized to deduct any necessary amounts from Deposit Account No. 08-1934, Order No. 36677.29.

2.3 THE INDEFINITENESS REJECTIONS ARE OVERCOME.

The Action at pages 2-4 rejected claims 8-19 and 44-50 under 35 U. S. C. § 112, 2nd paragraph, allegedly as being indefinite.

Claim 8 (and its dependencies) was rejected allegedly as indefinite for recitation of the language “optionally step (d),” where (d) is the step of removing A1 and A2.

Claim 11 and its dependency, claim 12, were rejected as allegedly indefinite because claim 8 recites a method of synthesis that encompasses compounds of General Formula I or II that do not contain an A1 or A2 group, yet claims 11 and 12 indicate that A1 and/or A2 (in certain embodiments) may remain attached to the peptide.

Claim 18 was rejected allegedly as indefinite for recitation of the term “A2 is an irreversible substituent” since the Examiner considers the language to be inconsistent with the limitation for a compound of General Formula I or II as recited in claim 8.

Claims 46 and 48 were also rejected allegedly as indefinite because “the structures of A2 in the claim contain and NH₂ group, it is not clear where is the site for A2 to attach to the peptide” (*sic*).

For each of these rejections, Applicants respectfully traverse. However, in the interest of proceeding claims of particular relevance to issuance, to maximize patent term, and to avoid the financial consequences and time delays inherent with a protracted prosecution, Applicants have nevertheless amended claims 8, 11, 12, 18, 46 and 48 to impart improved clarity to the claim language, and to specifically address each of the Examiner’s concerns. Applicants explicitly note for the record, however, that none of the accompanying amendments was made to distinguish the claims over any prior art of record in the application. The amendments have been made only with respect to improving the clarity of the claim language itself, in an effort to more precisely point out and distinctly claim that which Applicants regard as their invention.

To that end, the language of claim 8 has been improved to provide more clarity with respect to requiring removal of both the A1 and A2 groups in step (d) of the method to generate compounds of General Formula I or General Formula II.

Claim 11 is now clarified to recite a method in which step (d) from the method of claim 8 is alternatively omitted to provide scenarios under which either the A1, the A2, or both the A1 and the A2 groups are left on the cyclic peptide or peptidomimetic compound of General

Formula V to provide means for later attaching such a compound to (a) a solid support or (b) to another cyclic peptide or peptidomimetic compound (as exemplified in the Specification at page 16). In exemplary embodiments, the A1 group can be a reversible N-substituent, and the A2 group may be a covalently-bonded group of atoms comprising a reactive functionality that forms an initial large cyclic peptide, wherein the A2 group is spontaneously eliminated as a result of ring contraction. The language of claim 12 is also further clarified to recite particular illustrative embodiments as set forth in the general Markush recitation found in claim 11, the claim from which it depends.

The language of claim 18 has also been clarified to more particularly and distinctly claim a method in which “A2 is removed after ring contraction,” or is “eliminated spontaneously upon ring contraction.” Applicants believe this improved language more distinctly identifies this particular aspect of the invention.

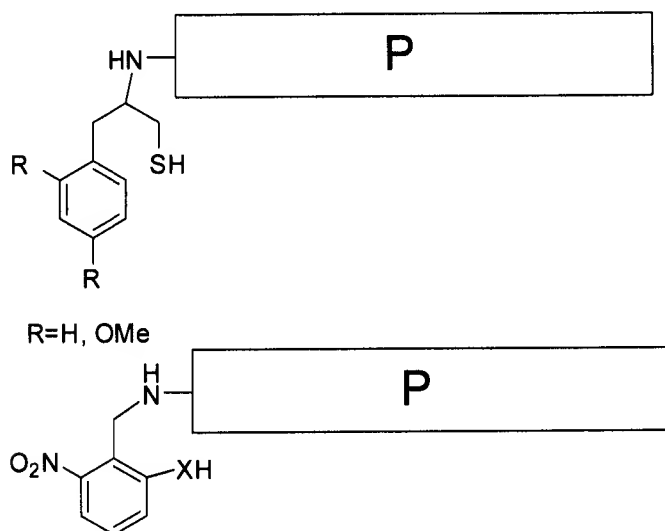
Finally, claims 46 and 48 have been clarified to more precisely recite a method in which selected ring contraction auxiliaries may be used to generate the A2 group which then facilitates the spontaneous ring contraction that forms the final cyclic peptide or peptidomimetic. Applicants draw the Examiner’s attention to pages 36-38 of the specification, wherein an exemplary use of such ring contraction auxiliaries is clearly explained. Applicants also note that certain compounds (*e.g.*, 6-nitrobenzyl-2-hydroxy derivatives) may act in the dual role of both a backbone substituent, and a ring contraction auxiliary (see *e.g.*, Example 3). Scheme 8 on page 52 of the specification particularly demonstrates that such compounds may provide particular facility for preparation of cyclic peptides using the claimed methods, as the single auxiliary/backbone compound can be removed from the cyclic peptide by photolysis.

As illustrated on page 52 of the specification, the auxiliary may be attached to the peptide *via* the N-bond of the N-terminal amino acid, from which it is then removed once the amino and carboxyl ends of the peptide are cyclized.

The auxiliary may also be attached to the peptide amine *via* reductive amination of an aldehyde. Such is illustrated in claim 48, which exemplifies various intermediates within the reaction pathway. Applicants note that the skilled artisan would appreciate that the next step in the process would be that of cyclization, which Applicants also note may be performed, for example, by reductive amination of the aldehyde of the auxiliary to the amine of the peptide.

Applicants emphasize, however, that reductive amination is only *one* way of attaching an auxiliary to a peptide. Applicants assert that it would be readily appreciated by a person of skill in the art that the same intermediate could be prepared by using different chemistries to attach to the amine.

To further clarify this issue for the Office, Applicants note that the ultimate product (prior to cyclization), can be prepared without any restriction on how the auxiliary itself can be attached to the peptide. This fact is illustrated schematically below:



Applicants believe that the present amendment fully addresses the concerns of the Examiner, and respectfully requests therefore, that the rejection of the cited claims for indefiniteness now be withdrawn.

2.4 CONCLUSION

It is respectfully submitted that all claims are now fully-acceptable under the Statutes and are in conditions for ready allowance. Applicants respectfully request, therefore, the withdrawal of all rejections and that a Notice of Allowance be issued in the case with all due speed.

Should any issues remain in the mind of the Examiner, or should any claims remain rejected for any reason following entry of the present amendment and consideration of the remarks and response herein, Applicants respectfully request that pursuant to M. P. E. P. §§ 408 and 713.09, the Examiner contact the undersigned representative to arrange a telephonic Examiner Interview at a mutually-convenient time to discuss favorable disposition of the case, and the resolution of any remaining issues.

Applicants again note for the record their right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing and/or divisional application(s) that retain the priority claim of the pending application.

Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated and in particular in advance of any subsequent action on the merits.

Respectfully submitted,



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